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(54) Title: COMPOSITIONS COMPRISING ARABINOGALACTAN AND A DEFINED PROTEIN COMPONENT

(57) Abstract: The present disclosure relates to compositions comprising arabinogalactan and a component selected from dairy protein, soy protein, and mixtures thereof. The compositions are useful for stabilizing the defined protein components in the presence of fiber, optionally at low pH. In particular, the present compositions comprise arabinogalactan and a defined protein component, particularly dairy protein or soy protein, without compromising taste, appearance, stability, and/or bioavailability.

## COMPOSITIONS COMPRISING ARABINOGALACTAN AND A DEFINED PROTEIN COMPONENT

### CROSS REFERENCE TO RELATED APPLICATION

This invention claims priority to U.S. Provisional Application Serial No. 60/236,502, filed September 29, 2000, entitled "Beverage Compositions Comprising Arabinogalactan and Defined Minerals" and U.S. Provisional Application Serial No. 60/236,507, filed September 29, 2000, entitled "Beverage Compositions Comprising Arabinogalactan and Defined Vitamins."

### FIELD OF THE INVENTION

The present invention is directed to compositions useful for stabilizing defined protein components in the presence of fiber, optionally at low pH. In particular, the present compositions comprise arabinogalactan and a defined protein component, particularly dairy protein or soy protein, without compromising taste, appearance, stability, and / or bioavailability.

### BACKGROUND OF THE INVENTION

The addition of fiber to various food, beverage, and other ingestible products is known to be highly advantageous for various health benefits, particularly those benefits associated with enhanced gastrointestinal health, lowered cholesterol, and even prevention of cancer or other diseases. However, the addition of fiber to certain ingestible forms can be problematic. This may be a particular issue where it is desired that protein components are also delivered, as such protein components will typically cause gelling or complexing of the fiber. For instance, the addition of one or more soluble fibers such as pectin or psyllium can cause gelling, increased viscosity, flocculation, separation, and decreased mineral bioavailability.

Additionally, wherein the protein component (*e.g.*, a dairy protein) also delivers various minerals such as calcium, this gelling and complexing is even further exacerbated. In addition, these occurrences can compromise product flavor (particularly through the causation of grit or other insolubles in the formulation) or cause off-color development. For example, use of such minerals can cause significant off-flavors such as rancidity and a metallic aftertaste. Such problems are readily apparent to the consumer and will often preclude the consumer from ingesting a mineral-supplemented composition. Additionally, it is well established that the addition of various bioavailable iron sources such as ferrous sulfate and ferrous fumarate to flavored milk-based products (*e.g.*, chocolate milk) can cause off-color and off-flavor

development. Accordingly, there are various challenges associated with the formulation an ingestible form which contains the benefits of fiber, protein, and a mineral.

Additionally, it is known that the use of dairy and other proteins below their isoelectric points is particularly problematic. Specifically, dairy proteins will often agglomerate or curdle when formulated below their isoelectric point and will become denatured, making such proteins unsuitable for use.

Quite surprisingly, the present inventors have discovered that the above described problems are overcome through use of a fiber known as arabinogalactan. In particular, it has been surprisingly discovered that the combination of arabinogalactan together with a dairy and / or soy protein results in an ingestible form which is not compromised in terms of its stability. For example, it has been discovered that the addition of fiber to such proteins does not cause gelling or agglomeration, even under pH conditions which would normally exacerbate the expected problems. Without intending to be limited by theory, it is believed that the arabinogalactan actually reduces the ability of the proteins (other mineral components contained inherently thereby) to react when in combination with the fiber itself or other ingredients present in the ultimate formulation.

As further benefits to this surprising discovery, use of the arabinogalactan provides a dietary fiber benefit to the consumer (e.g., prevention of constipation), as well as additional benefits in the field of immune function. It is therefore quite exciting that this fiber may be used not only to provide these benefits, but to also overcome the foregoing problems associated with protein / fiber (and also mineral) interactions, stabilization of minerals, and prevention of off-color and off-flavor development. As an even further benefit, use of a fiber to attempt these purposes would typically result in increased viscosity and likely unacceptability of the final product. However, it has further been found that the arabinogalactan fiber is not precluded from use due to any problems associated with viscosity.

Accordingly, the present invention enables the combination of the benefits of fiber (arabinogalactan) together with the benefits of protein (both dairy and soy), at all pH ranges, without introducing formulation feasibility issues. Furthermore, the present invention enables the delivery of minerals such as (for example) calcium, magnesium, zinc, or iron in a flavored dairy or soy product without the development of undesirable color and flavor. This and other benefits of the present invention are described herein.

#### SUMMARY OF THE INVENTION

The present invention relates to compositions comprising:

- a) a first component which is arabinogalactan; and
- b) a second component which is selected from the group consisting of dairy protein, soy protein, and mixtures thereof;

wherein when the second component comprises dairy protein, the composition is substantially free of yogurt.

### DETAILED DESCRIPTION OF THE INVENTION

Publications and patents are referred to throughout this disclosure. All references cited herein are hereby incorporated by reference.

All percentages and ratios are calculated by weight unless otherwise indicated. All percentages and ratios are calculated based on the total composition unless otherwise indicated.

All component or composition levels are in reference to the active level of that component or composition, and are exclusive of impurities, for example, residual solvents or by-products, which may be present in commercially available sources.

Referred to herein are trade names for components including various ingredients utilized in the present invention. The inventors herein do not intend to be limited by materials under a certain trade name. Equivalent materials (*e.g.*, those obtained from a different source under a different name or reference number) to those referenced by trade name may be substituted and utilized in the methods herein.

In the description of the invention various embodiments and / or individual features are disclosed. As will be apparent to the ordinarily skilled practitioner, all combinations of such embodiments and features are possible and can result in preferred executions of the present invention.

The compositions herein may comprise, consist essentially of, or consist of any of the elements as described herein.

### Compositions of the Present Invention

The compositions of the present invention comprise:

- (a) a first component which is arabinogalactan; and
- (b) a second component which is selected from the group consisting of dairy protein, soy protein, and mixtures thereof.

The present compositions are useful to provide beverages containing fiber and the health benefits of dairy and / or soy protein. Such beverages enable the health benefits of milk or soy together with fiber, including fighting infection, promoting healthy bacteria, and providing a

desired dietary fiber benefit. Surprisingly, these and other benefits of the present invention are achieved without compromising the physical integrity of the beverage, *i.e.*, the stability of the dairy and / or soy protein is not compromised, which is actually contrary to typical interactions between dietary fiber materials and these types of proteins. Further surprisingly, these benefits are even achieved at low pH, which is known in the art to exacerbate the problems associated with stabilization of protein components. For example, in the art, milk proteins are known to coagulate at pH levels below their isoelectric points resulting undesirable precipitates in acidified beverages.

#### First Component

The first component of the present compositions is arabinogalactan. The arabinogalactan present as the first component is additional to any arabinogalactan which is present in the composition by virtue of arabinogalactan inherently contained in the second component herein (dairy and / or soy protein). For example, soy protein may contain arabinogalactan as a "soy fiber" (see, for example, U.S. Patent No. 6,241,996, Hahn, issued June 5, 2001); the arabinogalactan referred to herein is additional to any such soy fiber.

Arabinogalactan is a polysaccharide which varies in molecular weight from low molecular weight polymers to large macromolecules. Arabinogalactan is also commonly referred to as larch gum, larch wood sugar, galactoarabinan, L-arabino-D-galactan, and stractan. Arabinogalactan is obtained from several plant and tree sources including, for example, the genus *Larix* (also referred to as *Larex*) which may contain up to about 35% of arabinogalactan within the total heartwood of some species. See Stout, "Larch Arabinogalactan", *Industrial Gums*, R.L. Whistle Ed., Academic Press, New York, pp. 307 - 310 (1959). Preferably, the arabinogalactan used herein is derived from tree sources of the genus *Larix*, particularly the species referred to as the Western larch (*Larix occidentalis*). Non-limiting examples of arabinogalactan sources include the Western larch (*Larix occidentalis*), Tamarack (also referred to as the Eastern larch, *Larix laricina*), Alpine larch (*Larix lyallii*), European larch (*Larix decidua*), Mongolian larch (*Larix dahurica*), Japanese larch (*Larix leptolepis*), and Siberian larch (*Larix siberica*). Numerous other trees, woody plants and root crops also contain arabinogalactan as part of their cell wall. For example, other suitable sources of arabinogalactan include hemlock, black spruce, douglas fir, cedar, juniper, sugar maple, radishes, carrots, onions, soy bean, and green coffee beans. Additionally, arabinogalactan is found in botanicals, for example, echinacea and mistletoe.

The structure of arabinogalactan has been extensively studied. See e.g., Timell, *Adv. Carbohydrate Chem.*, Vol. 20, pp. 409 - 483 (1965). Arabinogalactan is a polysaccharide containing *beta*-(1,3)-linked galactan backbone with side chains containing arabinose and

galactose residues, and often other minor residues. Preferably, the ratio of arabinose residues to galactose residues is from about 0.1:1 to about 1:1. Arabinogalactan includes naturally occurring or synthetic arabinogalactan, portions of arabinogalactan (such as degradation products), and chemically or biochemically modified arabinogalactan or portions thereof (as described below). Preferably, the arabinogalactan is a naturally occurring arabinogalactan, isolated from one or more natural sources. As also used herein "refined arabinogalactan" means arabinogalactan having a purity greater than about 95%, preferably greater than about 99%. Refined arabinogalactan of greater than about 95% purity, and even greater than about 99% purity, for example LAREX UF and LARACARE A200) is commercially available from (for example) Larex International, Inc. of St. Paul, Minnesota, U.S.A.

In a preferred embodiment, the molecular weight of arabinogalactan is from about 1,000 to about 2,500,000, more preferably from about 6,000 to about 300,000, even more preferably from about 10,000 to about 100,000, and most preferably from about 10,000 to about 50,000. Molecular weight may be assessed by standard means including, for example, size exclusion liquid chromatography.

Non-limiting examples of preferred, commercially available sources of arabinogalactan include LAREX UF, LARACARE A200, IMMUNENHANCER (CAS No. 9036-66-2), CLEARTRAC, FIBERAID, and AC-9, all commercially available from (for example) Larex International, Inc. of St. Paul, Minnesota, U.S.A.

Arabinogalactan is water soluble over a wide range of temperatures. The arabinogalactan molecule likely has a spherical shape when dissolved in water. Increasing concentrations of arabinogalactan have been found to lower the interfacial tension between water and mineral oil. Arabinogalactan remains soluble even at high concentrations, resulting in stable, low viscosity solutions.

Modified arabinogalactan is also useful in the present invention, and is within the definition of arabinogalactan as is used herein. Such modified arabinogalactan includes lipidated arabinogalactan which is described in Richards, WO 98/22512, assigned to the University of Montana, published May 28, 1998. In such example, lipidated arabinogalactan refers to a naturally occurring arabinogalactan covalently attached to a lipophilic group. Preferred lipophilic groups include long chain (*i.e.*, at least about 8 carbon atoms) hydrocarbon groups. Other lipophilic groups include steroids, terpenes, fat soluble vitamins, phytosterols, terpenoids, phospholipids, glycerols, and natural or synthetic fats. The lipophilic group may be attached directly to the natural arabinogalactan or *via* a linking group. Other non-limiting examples of

modified arabinogalactans include those described in Mak *et al.*, WO 99/55736, assigned to Larex, Inc., published November 4, 1999 (referred to as "arabinogalactan derivatives").

Various methods have been developed for recovering arabinogalactan from natural sources. Typically, arabinogalactan is recovered from tree sources (*e.g.*, a tree of the genus *Larix*) by chipping or grinding the wood and extracting it with water or dilute acidic solutions. The arabinogalactan extract obtained from the wood may be purified to obtain a highly refined arabinogalactan solution required in various commercial uses. Particularly preferred, although non-limiting, processes for obtaining arabinogalactan from natural sources are set forth in Price *et al.*, U.S. Patent No. 5,756,098, assigned to the University of Montana, Larex International, Inc., and Crown Iron Works Co., issued May 26, 1998, as well as Adams *et al.*, U.S. Patent No. 5,116,969, assigned to Larex International, Inc., issued May 26, 1992. For example, the fibrous natural material is compressed in the substantial absence of any added solvent to product a liquid exudate and a "first" pressed product. The "first" pressed product may be impregnated with, for example, an aqueous solvent, to recover a liquid pressate and a "second" pressed product. Using this process, a substantially pure arabinogalactan exudate can be produced. Example 1 of Price *et al.* sets forth a non-limiting example demonstrating extraction of arabinogalactan from Western larch.

The compositions of the present invention preferably comprise from about 0.0001% to about 75% arabinogalactan, more preferably from about 0.01% to about 50% arabinogalactan, still more preferably from about 0.01% to about 15% arabinogalactan, even more preferably from about 0.1% to about 10% arabinogalactan, and most preferably from about 0.1% to about 4% arabinogalactan, all by weight of the composition. Alternatively, the compositions preferably comprise from about 0.1 milligrams to about 40 grams of arabinogalactan, more preferably from about 500 milligrams to about 5 grams of arabinogalactan, all per 250 milliliters of the composition. As used herein, the amounts and levels of arabinogalactan described herein are exclusive of any arabinogalactan which is present in the composition by virtue of arabinogalactan inherently contained in the second component herein (dairy and / or soy protein).

#### Second Component

The second component is selected from the group consisting of dairy protein, soy protein, and mixtures thereof; wherein when the second component comprises dairy protein, the composition is substantially free of yogurt. As is well known in the art, yogurt is made by inoculating certain bacteria, typically *Streptococcus thermophilus*, *Lactobacillus acidophilus*, and / or *Lactobacillus bulgaricus*, into milk (this process is commonly referred to in the art as

fermentation). Upon inoculation, the milk is incubated until firm and the milk becomes coagulated by bacteria-produced lactic acid. It has been surprisingly discovered that the arabinogalactan utilized herein stabilizes dairy and / or soy proteins without relying on the coagulation or thickness associated with use of the yogurt which can hold various fibers in place by virtue of its viscosity or natural gelling. Thus, surprisingly, the present invention is useful for the stabilization of dairy and / or soy protein in the presence of fibers, preferably without reliance on the coagulation or gelling of yogurt.

The dairy protein which may be utilized in the present invention is commonly known in the art. Dairy protein may include, for example, all forms of milk (*e.g.*, mammalian or vegetable source). Milk includes, but is not limited to, whole milk, skim milk, condensed milk, non-fat milk, and milk solids (all of which may be fat or non-fat). Again, wherein dairy protein is used, the composition is substantially free of yogurt (*i.e.*, cultured or fermented milk). Most preferably, the composition is substantially free of yogurt regardless of whether dairy or soy protein is used. By "substantially free of yogurt," it is meant that the composition comprises less than about 1 million bacteria per gram of the composition, preferably less than about 500,000 bacteria per gram of the composition, even more preferably less than about 200,000 bacteria per gram of the composition, and most preferably less than about 100,000 bacteria per gram of the composition. Typical yogurts contain about 1 billion bacteria per gram of the yogurt. See James M. Jay, *Modern Food Microbiology*, 4<sup>th</sup> Ed., Chapman & Hall, p. 379 (1992). As used herein, the term "bacterial" shall include both live and dead bacteria. In contrast with fermentation involving bacteria, the present invention may be made by a variety of processes (as described below), including (for example) direct acidification.

Preferably, wherein dairy protein is utilized, the composition comprises from about 0.01% to about 20%, more preferably from about 0.1% to about 15%, even more preferably from about 0.5% to about 10%, and most preferably from about 0.5% to about 5% of dairy protein, wherein the amounts are expressed in terms of milk solids, by weight of the composition.

Soy protein may also be utilized as the second component, either alone or in combination with the dairy protein. The soy protein is commonly known in the art and may be in the form of, for example, soy protein isolate, soy protein concentrate, and / or soy flour. These forms are also well known. For example, soy flour may be produced from ground soybeans after removal of oil and typically contains more than about 50% protein on a dry-weight basis. Soy protein concentrate is further refined through the removal of most non-protein components, and typically contains more than about 65% protein on a dry-weight basis. Soy protein isolate typically contains more than about 90% protein on a dry-weight basis. Soy protein isolate is the most



preferred soy protein form utilized herein due to its high protein content. All of these forms will typically contain isoflavones and phytosterols, which have been associated with various health benefits such as serum cholesterol reduction, and improvement of hormonal imbalance.

Preferably, wherein soy protein is utilized, the composition comprises from about 0.01% to about 50%, more preferably from about 0.1% to about 25%, even more preferably from about 1% to about 15%, and most preferably from about 2% to about 12% of soy protein, wherein the amounts are expressed in terms of soy protein isolate, by weight of the composition.

## pH

As has been stated, the combination of various protein components with fiber has been problematic in the art. The discovery described herein alleviates these associated problems through the use of arabinogalactan fiber in combinations with soy or dairy protein. While low pH typically further exacerbates the known problems, it has been additionally discovered that the present invention prevents the gelling, denaturing, and other stability issues normally mediated by a low pH environment. Accordingly, pH ranges of the present compositions may be freely adjusted due to the problems solved through the present invention. For example, the present compositions may have a pH of from about 2 to about 9. The compositions may have a low pH, *i.e.*, from about 2 to about 5, more preferably from about 2.5 to about 4. At acidic pH, it has been discovered that the present invention is optimally utilized at a pH of from about 3 to about 3.5. If also desired, slightly acidic, neutral, or high pH may be utilized, for example from about 5 to about 8, preferably from about 5 to about 7. An optimal pH range has also been discovered in the slightly acidic to near neutral range, which is from about 6 to about 7.

Accordingly, if desired, the present compositions may optionally comprise one or more acidulants without compromising the stability of the protein. Beverage acidity can be adjusted to and maintained within the requisite range by known and conventional methods, *e.g.*, the use of one or more acidulants. Typically, acidity within the above recited ranges is a balance between maximum acidity for microbial inhibition and optimum acidity for the desired beverage flavor.

Organic as well as inorganic edible acids may be used to adjust the pH of the beverage. The acids can be present in their undissociated form or, alternatively, as their respective salts, for example, potassium or sodium hydrogen phosphate, potassium or sodium dihydrogen phosphate salts. The preferred acids are edible organic acids which include citric acid, malic acid, fumaric acid, adipic acid, phosphoric acid, gluconic acid, tartaric acid, ascorbic acid, acetic acid, phosphoric acid or mixtures thereof. The most preferred acids are citric and malic acids.

The acidulant can also serve as an antioxidant to stabilize beverage components. Examples of commonly used antioxidant include but are not limited to ascorbic acid, EDTA (ethylenediaminetetraacetic acid), and salts thereof.

Additionally, certain basic components may be utilized to adjust the pH of the composition. Such basic components are commonly known in the art.

However, acidic or basic components need not be used. For example, the present compositions may inherently have a pH which ranges from about 5 to about 8 without use of any components which tend to modify such pH.

#### Other Optional Components of the Present Compositions

As stated, the compositions of the present invention may be utilized in various forms such as beverage compositions or food compositions (e.g., bars, soups), most preferably beverage compositions. As will be well understood, beverage compositions include ready-to-drink beverages, beverage concentrates and dry beverage compositions. As used herein, "dry beverage compositions" are substantially dry (meaning, comprising from 0% to about 4%, preferably from 0% to about 3% water) compositions which are suitable for dilution with water or other liquids to form a beverage concentrate or ready-to-drink beverage. Ready-to-drink beverages and beverage concentrates are widely known in the art. As will be well understood, beverage compositions may be of a variety of different forms, and for a variety of different purposes. Non-limiting examples of typical beverages include refreshment beverages, nutritional beverages, meal replacement beverages, weight loss beverages, and the like.

Consistent with the various uses herein, the compositions of the present invention may comprise other optional components to enhance, for example, their performance in providing one or more of the foregoing health benefits (for example, fighting infection), providing a desirable nutritional profile including the health benefits of dairy or soy protein, and / or providing enhanced organoleptic properties. For example, one or more flavanols, non-caloric sweeteners, vitamins, minerals, emulsions, flavoring agents, coloring agents, preservatives, water, carbonation components, and / or the like may be included in the compositions herein. Such optional components may be dispersed, solubilized, or otherwise mixed into the present compositions. Non-limiting examples of optional components suitable for use herein are given below.

#### Flavanols

Flavanols are natural substances present in a variety of plants (e.g., fruits, vegetables, and flowers). The flavanols which may be utilized in the present invention can be extracted from, for example, fruit, vegetables, green tea or other natural sources by any suitable method well known to those skilled in the art. For example, extraction with ethyl acetate or chlorinated organic solvents is a common method to isolate flavanols from green tea. Flavanols may be extracted from either a single plant or mixtures of plants. Many fruits, vegetables, and flowers contain flavanols but to a lesser degree relative to green tea. Plants containing flavanols are known to those skilled in the art. Examples of the most common flavanols which are extracted from tea plants and other members of the *Catechu gambir* (Uncaria family) include, for example, catechin, epicatechin, gallic catechin, epigallocatechin, epicatechin gallate, and epigallocatechin gallate.

The flavanols utilized in all compositions of the present invention can be in the form of a tea extract. The tea extract can be obtained from the extraction of unfermented teas, fermented

teas, partially fermented teas, and mixtures thereof. Preferably, the tea extracts are obtained from the extraction of unfermented and partially fermented teas. The most preferred tea extracts are obtained from green tea. Both hot and cold extracts can be used in the present invention. Suitable methods for obtaining tea extracts are well known. See e.g., Ekanayake, U.S. Patent No. 5,879,733, issued March 9, 1999; Tsai, U.S. Patent No. 4,935,256, issued June, 1990; Lunder, U.S. 4,680,193, issued July, 1987; and Creswick, U.S. Patent No. 4,668,525, issued May 26, 1987.

The preferred source of flavanols in the compositions of the present invention is green tea. Wherein green tea, and in particular the flavanols present in green tea, are incorporated into the beverage, the present inventors have discovered that the flavanols are at least partially responsible for delaying the bioavailability of bracers, which contributes to the reduction and / or elimination of nervousness and tension typically associated with such bracers.

Alternatively, these same flavanols may be prepared by synthetic or other appropriate chemical methods and incorporated into the present compositions. Flavanols, including catechin, epicatechin, and their derivatives are commercially available.

The amount of flavanols in the compositions of the present invention can vary. However, wherein one or more flavanols are utilized, preferably from about 0.001% to about 5%, more preferably from about 0.001% to about 2%, even more preferably from about 0.01% to about 1%, and most preferably from about 0.01% to about 0.05% of one or more flavanols is utilized, by weight of the composition.

#### Sweeteners

The compositions of the present invention can, and typically will, contain an effective amount of one or more sweeteners, including carbohydrate sweeteners and natural and/or artificial no/low calorie sweeteners. The amount of the sweetener used in the beverages of the present invention typically depends upon the particular sweetener used and the sweetness intensity desired. For no/low calorie sweeteners, this amount varies depending upon the sweetness intensity of the particular sweetener.

The compositions of the present invention can be sweetened with any of the carbohydrate sweeteners, preferably monosaccharides and / or disaccharides. Sweetened beverages will typically comprise from about 0.1% to about 20%, most preferably from about 6 to about 14%, sweetener. These sugars can be incorporated into the beverages in solid or liquid form but are typically, and preferably, incorporated as a syrup, most preferably as a concentrated syrup such as high fructose corn syrup. For purposes of preparing beverages of the present invention, these

sugar sweeteners can be provided to some extent by other components of the beverage such as, for example, the fruit juice component and / or flavors.

Preferred sugar sweeteners for use in beverage products of the present invention are sucrose, fructose, glucose, and mixtures thereof, particularly sucrose and fructose. Fructose can be obtained or provided as liquid fructose, high fructose corn syrup, dry fructose or fructose syrup, but is preferably provided as high fructose corn syrup. High fructose corn syrup (HFCS) is commercially available as HFCS-42, HFCS-55 and HFCS-90, which comprise 42%, 55% and 90%, respectively, by weight of the sugar solids therein, as fructose. Other naturally occurring sweeteners or their purified extracts, such as glycyrrhizin, stevioside, the protein sweetener thaumatin, the juice of Luo Han Guo (containing the sweet mogrosides) disclosed in, for example, Fischer et al., U. S. Patent No. 5,433,965, issued July 18, 1995, and the like can also be used in the beverages of the present invention.

Effective levels of non-caloric sweeteners may optionally be used in the compositions of the present invention to further sweeten such compositions. Non-limiting examples of non-caloric sweeteners include aspartame, saccharine, cyclamates, acesulfame K, L-aspartyl-L-phenylalanine lower alkyl ester sweeteners, L-aspartyl-D-alanine amides such as, for example, those disclosed in Brennan *et al.*, U.S. Patent No. 4,411,925, issued 1983, L-aspartyl-D-serine amides such as, for example, those disclosed in Brennan *et al.*, U.S. Patent No. 4,399,163, issued 1983, L-aspartyl-hydroxymethyl alkane amide sweeteners such as, for example, those disclosed in Brand, U.S. Patent No. 4,338,346, issued 1982, L-aspartyl-1-hydroxyethylalkane amide sweeteners such as, for example, those disclosed in Rizzi, U.S. Patent No. 4,423,029, issued 1983, glycyrrhizins, and synthetic alkoxy aromatics. Aspartame and acesulfame-K are the most preferred non-caloric sweeteners utilized herein, and may be utilized alone or in combination.

Wherein one or more sweeteners are utilized herein, the total non-caloric sweetener is preferably utilized at levels from about 0.0001% to about 5%, more preferably from about 0.001% to about 3%, still more preferably from about 0.005% to about 2%, even more preferably from about 0.01% to about 1%, and most preferably from about 0.01% to about 0.05%, by weight of the composition.

#### Vitamins

The compositions herein may optionally be fortified with one or more vitamins.

The U.S. Recommended Daily Intake (USRDI) for vitamins and minerals is defined and set forth in the Recommended Daily Dietary Allowance-Food and Nutrition Board, National Academy of Sciences-National Research Council. Unless otherwise specified herein, wherein a given vitamin is present in the composition, the composition comprises at least about 1%,

preferably at least about 5%, more preferably from about 10% to about 200%, even more preferably from about 20% to about 150%, and most preferably from about 25% to about 120% of the USRDI of such vitamin.

Non-limiting examples of vitamins include vitamin A, one or more B-complex vitamins (which include one or more of thiamine (also commonly referred to as "vitamin B<sub>1</sub>"), riboflavin (also commonly referred to as "vitamin B<sub>2</sub>"), niacin (also commonly referred to as "vitamin B<sub>3</sub>"), pantothenic acid (also commonly referred to as "vitamin B<sub>5</sub>"), pyridoxine (also commonly referred to as "vitamin B<sub>6</sub>"), biotin, folic acid (also commonly referred to as folate), and the cobalamins (also commonly referred to as "vitamin B<sub>12</sub>")), vitamin C, vitamin D, and vitamin E. Preferably, wherein a vitamin is utilized the vitamin or mineral is selected from vitamin A, niacin, thiamine, folic acid, pyroxidine, pantothenic acid, vitamin C, vitamin E, and vitamin D. Preferably, at least one vitamin is selected from vitamin A, thiamine, pyroxidine, pantothenic acid, vitamin C, and vitamin E.

As used herein, "vitamin A" is inclusive of one or more nutritionally active unsaturated hydrocarbons, including the retinoids (a class of compounds including retinol and its chemical derivatives having four isoprenoid units) and the carotenoids.

Common retinoids include retinol, retinal, retinoic acid, retinyl palmitate, and retinyl acetate.

In a preferred embodiment herein, the vitamin A is a carotenoid. Common carotenoids include *beta*-carotene, *alpha*-carotene, *beta*-apo-8'-carotenal, cryptoxanthin, canthaxanthin, astacene, and lycopene. Among these, *beta*-carotene is the most preferred for use herein.

The vitamin A may be in any form; for example, an oil, beadlets, or encapsulated. See e.g., Cox *et al.*, U.S. Patent No. 6,007,856, assigned to The Procter & Gamble Co., issued December 28, 1999. Vitamin A is often available as an oil dispersion, *i.e.*, small particles suspended in oil.

Wherein vitamin A is present in the compositions herein, the composition typically comprises, per single serving of the composition (typically, about 240 milliliters of total composition), at least about 1%, preferably at least about 5%, more preferably from about 10% to about 200%, even more preferably from about 15% to about 150%, and most preferably from about 20% to about 120% of the USRDI of such vitamin. Wherein vitamin A is present in the compositions herein, it is especially preferred to include about 25% of the USRDI of vitamin A, per single serving of the composition. Alternatively, the compositions preferably comprise from 0% to about 1%, more preferably from about 0.0002% to about 0.5%, also preferably from about 0.0003% to about 0.25%, even more preferably from about 0.0005% to about 0.1%, and most

preferably from about 0.001% to about 0.08% of vitamin A, by weight of the composition. The ordinarily skilled artisan will understand that the quantity of vitamin A to be added is dependent on processing conditions and the amount of vitamin A delivery desired after storage.

As stated the vitamin used herein may be a B-complex vitamin. As used herein, the B-complex vitamins include one or more of thiamine (also commonly referred to as "vitamin B<sub>1</sub>"), riboflavin (also commonly referred to as "vitamin B<sub>2</sub>"), niacin (also commonly referred to as "vitamin B<sub>3</sub>"), pantothenic acid (also commonly referred to as "vitamin B<sub>5</sub>"), pyridoxine (also commonly referred to as "vitamin B<sub>6</sub>"), biotin, folic acid (also commonly referred to as folate), and the cobalamins (also commonly referred to as "vitamin B<sub>12</sub>"). Among these, inclusion of vitamin B<sub>1</sub> and / or B<sub>6</sub> are particularly preferred.

Wherein a B-complex vitamin is present in the compositions herein, the composition typically comprises at least about 1%, preferably at least about 5%, more preferably from about 10% to about 200%, even more preferably from about 15% to about 150%, and most preferably from about 20% to about 120% of the USRDI of each B-complex vitamin present in the composition, per single serving of the composition (typically, about 240 milliliters of total composition). Wherein a B-complex vitamin is present in the compositions herein, it is especially preferred to include from about 10% to about 50% of the USRDI of each B-complex vitamin present in the composition, per single serving of the composition. Alternatively, wherein a B-complex vitamin is included within the present compositions, the compositions typically comprise from 0% to about 2%, more preferably from about 0.0002% to about 1%, also preferably from about 0.0005% to about 0.2%, even more preferably from about 0.001% to about 0.1%, and most preferably from about 0.001% to about 0.1% of each B-complex vitamin present in the composition, by weight of the composition. The ordinarily skilled artisan will understand that the quantity of B-complex vitamin to be added is dependent on processing conditions and the amount of B-complex vitamin delivery desired after storage.

As used herein, "vitamin C" is inclusive of one or more of L-ascorbic acid, as well as their bioequivalent forms including salts and esters thereof. For example, the sodium salt of L-ascorbic acid is considered vitamin C herein. Additionally, there are many widely known esters of vitamin C, including ascorbyl acetate. Fatty acid esters of vitamin C are lipid soluble and can provide an antioxidative effect.

The vitamin C utilized may be in any form, for example, free or in encapsulated form.

Wherein vitamin C is present in the compositions herein, the composition typically comprises at least about 1%, preferably at least about 5%, more preferably from about 10% to about 200%, even more preferably from about 15% to about 150%, and most preferably from

about 20% to about 120% of the USRDI of such vitamin, per single serving of the composition (typically, about 240 milliliters of total composition). Wherein vitamin C is present in the compositions herein, it is especially preferred to include about 100% of the USRDI of vitamin C, per single serving of the composition. Alternatively, wherein vitamin C is included within the present compositions, the compositions typically comprise from 0% to about 2%, more preferably from about 0.0002% to about 1%, also preferably from about 0.0003% to about 0.5%, even more preferably from about 0.0005% to about 0.2%, and most preferably from about 0.001% to about 0.1% of vitamin C, by weight of the composition. The ordinarily skilled artisan will understand that the quantity of vitamin C to be added is dependent on processing conditions and the amount of vitamin C delivery desired after storage.

As used herein, "vitamin E" is inclusive of one or more tocopherols or tocotrienols which exhibit vitamin activity similar to that of *alpha*-tocopherol (which, as used herein, is considered a tocopherol) as well as their bioequivalent forms including salts and esters thereof. Vitamin E is typically found in oils including, for example, sunflower, peanut, soybean, cottonseed, corn, olive, and palm oils.

Non-limiting examples of vitamin E include *alpha*-tocopherol, *beta*-tocopherol, *gamma*-tocopherol, and *delta*-tocopherol, as well as esters thereof (e.g., *alpha*-tocopherol acetate). *Alpha*-tocopherol and particularly *alpha*-tocopherol acetate are highly preferred for use as vitamin E herein.

The vitamin E utilized may be in any form, for example, free or in encapsulated form. Wherein vitamin E is present in the compositions herein, the composition typically comprises at least about 1%, preferably at least about 5%, more preferably from about 10% to about 200%, even more preferably from about 15% to about 150%, and most preferably from about 20% to about 120% of the USRDI of such vitamin, per single serving of the composition (typically, about 240 milliliters of total composition). Wherein vitamin E is present in the compositions herein, it is especially preferred to include about 25% of the USRDI of vitamin E, per single serving of the composition. Alternatively, wherein vitamin E is included within the present compositions, the compositions typically comprise from 0% to about 2%, more preferably from about 0.0002% to about 1%, also preferably from about 0.0003% to about 0.2%, even more preferably from about 0.0005% to about 0.1%, and most preferably from about 0.001% to about 0.1% of vitamin E, by weight of the composition. The ordinarily skilled artisan will understand that the quantity of vitamin E to be added is dependent on processing conditions and the amount of vitamin E delivery desired after storage.

#### Minerals



As previously stated, the present compositions may optionally comprise one or more defined minerals. In using a dairy protein, for example, some minerals will be inherently present in the composition. Minerals may also optionally be added to the protein and arabinogalactan combination.

The United States Recommended Daily Intake (USRDI) for minerals is defined and set forth in the Recommended Daily Dietary Allowance-Food and Nutrition Board, National Academy of Sciences-National Research Council. Unless otherwise specified herein, wherein a given mineral is present in the composition, the composition typically comprises at least about 1%, preferably at least about 5%, more preferably from about 10% to about 200%, even more preferably from about 40% to about 150%, and most preferably from about 60% to about 125% of the USRDI of such mineral.

Minerals are well-known in the art. Non-limiting examples of such minerals include zinc, iron, magnesium, calcium, selenium, iodine, and fluoride. Preferably, wherein a mineral is utilized, the mineral is selected from zinc, magnesium, iron, iodine, and calcium. Most preferably, the mineral is selected from zinc, iron, magnesium, and calcium. Iron and calcium are particularly preferred for use herein. Minerals may be, for example, salts, chelated, complexed, encapsulated, or in colloidal form.

As used herein, "zinc" is inclusive of any compound containing zinc, including a salt, complex, or other form of zinc, including elemental zinc. Acceptable forms of zinc are well-known in the art. The zinc which can be used in the present invention can be in any of the commonly used forms such as, *e.g.*, zinc lactate, zinc sulfate, zinc chloride, zinc acetate, zinc gluconate, zinc ascorbate, zinc citrate, zinc aspartate, zinc picolinate, amino acid chelated zinc, and zinc oxide. Zinc gluconate and amino acid chelated zinc are particularly preferred. Additionally, it has been found that amino acid chelated zinc is most highly preferred, as this zinc form provides optimized bioavailability of the zinc, other minerals present within the composition, as well as optimizing the bioavailability of the arabinogalactan utilized in the composition.

Amino acid chelates of zinc are well-known in the art, and are described in, for example, Pedersen *et al.*, U.S. Patent No. 5,516,925, assigned to Albion International, Inc., issued May 14, 1996; Ashmead, U.S. Patent No. 5,292,729, assigned to Albion International, Inc., issued March 8, 1994; and Ashmead, U.S. Patent No. 4,830,716, assigned to Albion International, Inc., issued May 16, 1989. These chelates contain one or more natural amino acids selected from alanine, arginine, asparagine, aspartic acid, cysteine, cystine, glutamine, glutamic acid, glycine, histidine, hydroxyproline, isoleucine, leucine, lysine, methionine, ornithine, phenylalanine, proline, serine,

threonine, tryptophan, tyrosine and valine or dipeptides, tripeptides or quadrapeptides formed by any combination of these amino acids.

Additionally, encapsulated zinc is also preferred for use herein. For example, the zinc may be encapsulated with bilayer-forming emulsifiers. See Mehansho *et al.*, U.S. Patent No. 5,888,563, issued March 30, 1999.

Zinc fortified compositions of the present invention typically contain at least about 1 milligram of zinc, more preferably at least about 5 milligrams of zinc, and most preferably at least about 10 milligrams of zinc, all per single serving of the composition (typically, about 240 milliliters of total composition). Typically, from about 10 milligrams to about 25 milligrams of zinc per single serving is recommended. Alternatively, the present compositions preferably comprise from 0% to about 0.1% zinc, more preferably from about 0.001% to about 0.08% zinc, even more preferably from about 0.002% to about 0.05% zinc, and most preferably from about 0.002% to about 0.03% zinc, by weight of the composition. As used herein, recitations of mass or weight percent of zinc in any given composition refers to the mass or weight percent of the zinc-containing component (for example, the amino acid chelated zinc component), rather than the mass or weight percent of the elemental zinc which is part of the zinc-containing component. Of course, wherein elemental zinc is utilized as the zinc, the mass or weight percent of zinc in any given composition refers to that of the elemental zinc.

As used herein, "iron" is inclusive of any compound containing iron, including a salt, complex, or other form of iron, including elemental iron. Acceptable forms of iron are well-known in the art.

Non-limiting examples of ferrous iron sources which can be used in the present invention include ferrous sulfate, ferrous fumarate, ferrous succinate, ferrous gluconate, ferrous lactate, ferrous tartrate, ferrous citrate, ferrous amino acid chelates, and ferrous pyrophosphate, as well as mixtures of these ferrous salts. While ferrous iron is typically more bioavailable, certain ferric salts can also provide highly bioavailable sources of iron. Non-limiting examples of ferric iron sources that can be used in the present invention are ferric saccharate, ferric ammonium citrate, ferric citrate, ferric sulfate, ferric chloride, and ferric pyrophosphate, as well as mixtures of these ferric salts. A particularly preferred ferric iron source is ferric pyrophosphate, for example, microencapsulated SUNACTIVE Iron, commercially available from Taiyo International, Inc., Edina, Minnesota, U.S.A and Yokkaichi, Mie, Japan. SUNACTIVE Iron is particularly preferred for use herein due to its water-dispersibility, particle size, compatibility, and bioavailability.

Ferrous amino acid chelates particularly suitable as highly bioavailable amino acid chelated irons for use in the present invention are those having a ligand to metal ratio of at least

2:1. For example, suitable ferrous amino acid chelates having a ligand to metal mole ratio of two are those of formula:



where L is an alpha amino acid, dipeptide, tripeptide or quadrapeptide reacting ligand. Thus, L can be any reacting ligand that is a naturally occurring alpha amino acid selected from alanine, arginine, asparagine, aspartic acid, cysteine, cystine, glutamine, glutamic acid, glycine, histidine, hydroxyproline, isoleucine, leucine, lysine, methionine, ornithine, phenylalanine, proline, serine, threonine, tryptophan, tyrosine and valine or dipeptides, tripeptides or quadrapeptides formed by any combination of these amino acids. See e.g., Pedersen *et al.*, U.S. Patent No. 5,516,925, assigned to Albion International, Inc., issued May 14, 1996; Ashmead, U.S. Patent No. 5,292,729, assigned to Albion International, Inc., issued March 8, 1994; and Ashmead, U.S. Patent No. 4,830,716, assigned to Albion International, Inc., issued May 16, 1989. Particularly preferred ferrous amino acid chelates are those where the reacting ligands are glycine, lysine, and leucine. Most preferred is the ferrous amino acid chelate sold under the trade name FERROCHEL having the reacting ligand as glycine. FERROCHEL is commercially available from Albion Laboratories, Salt Lake City, Utah. Use of FERROCHEL herein is particularly useful wherein the composition is low pH.

In addition to these highly bioavailable ferrous and ferric salts, other sources of bioavailable iron can be included in the compositions of the present invention. Other sources of iron particularly suitable for fortifying compositions herein certain iron-sugar-carboxylate complexes. In these iron-sugar-carboxylate complexes, the carboxylate provides the counterion for the ferrous (preferred) or ferric iron. The overall synthesis of these iron-sugar-carboxylate complexes involves the formation of a calcium-sugar moiety in aqueous media (for example, by reacting calcium hydroxide with a sugar, reacting the iron source (such as ferrous ammonium sulfate) with the calcium-sugar moiety in aqueous media to provide an iron-sugar moiety, and neutralizing the reaction system with a carboxylic acid (the "carboxylate counterion") to provide the desired iron-sugar-carboxylate complex). Sugars that can be used to prepare the calcium-sugar moiety include any of the ingestible saccharidic materials, and mixtures thereof, such as glucose, sucrose and fructose, mannose, galactose, lactose, maltose, and the like, with sucrose and fructose being the more preferred. The carboxylic acid providing the "carboxylate counterion" can be any ingestible carboxylic acid such as citric acid, malic acid, tartaric acid, lactic acid, succinic acid, and propionic acid, as well as mixtures of these acids.

These iron-sugar-carboxylate complexes can be prepared in the manner described in Nakel *et al.*, U.S. Patent No. 4,786,510 and 4,786,518, issued November 22, 1988. These materials are referred to as "complexes", but they may, in fact, exist in solution as complicated, highly hydrated, protected colloids; the term "complex" is used for the purpose of simplicity.

Additionally, encapsulated iron is also preferred for use herein. For example, ferrous sulfate encapsulated in a hydrogenated soybean oil matrix may be used, for example, CAP-SHURE which is commercially available from Bachem Corp., Slate Hill, N.Y. Other solid fats can be used to encapsulate the iron, such as, tristearin, hydrogenated corn oil, cottonseed oil, sunflower oil, tallow, and lard. A particularly preferred encapsulated iron source is microencapsulated SUNACTIVE Iron, commercially available from Taiyo International, Inc., Edina, Minnesota, U.S.A. SUNACTIVE Iron is particularly preferred for use herein due to its water-dispersibility and bioavailability. Additionally, the iron (particularly, ferrous fumarate and ferrous succinate) may be encapsulated with bilayer-forming emulsifiers. See Mehansho *et al.*, U.S. Patent No. 5,888,563, issued March 30, 1999.

Iron fortified compositions of the present invention preferably contain at least about 1 milligram of iron, more preferably at least about 5 milligrams of iron, and most preferably at least about 10 milligrams of iron all per single serving of the composition (typically, about 240 milliliters of total composition). Typically, from about 10 milligrams to about 25 milligrams of iron is recommended per single serving. Alternatively, the present compositions comprise from 0% to about 0.1% iron, more preferably from about 0.0001% to about 0.08% iron, even more preferably from about 0.0002% to about 0.05% iron, and most preferably from about 0.0002% to about 0.03% zinc, by weight of the composition. As used herein, recitations of mass or weight percent of "iron" in any given composition refers to the mass or weight percent of the iron-containing component (for example, the amino acid chelated iron component), rather than the mass or weight percent of the elemental iron which is part of the iron-containing component. Of course, wherein elemental iron is utilized as the "iron", the mass or weight percent of iron in any given composition refers to that of the elemental iron.

As used herein, "magnesium" is inclusive of any compound containing magnesium, including a salt, complex, or other form of magnesium, including elemental magnesium. Acceptable forms of magnesium are well-known in the art.

Magnesium chloride, magnesium citrate, magnesium gluceptate, magnesium gluconate, magnesium hydroxide, magnesium lactate, magnesium oxide, magnesium picolate, and magnesium sulfate are non-limiting, exemplary forms of magnesium for use herein. Additionally, amino acid chelated and creatine chelated magnesium are highly preferred. Amino acid and

creatine chelates of magnesium are well-known in the art, and are described in, for example, Pedersen *et al.*, U.S. Patent No. 5,516,925, assigned to Albion International, Inc., issued May 14, 1996; Ashmead, U.S. Patent No. 5,292,729, assigned to Albion International, Inc., issued March 8, 1994; and Ashmead, U.S. Patent No. 4,830,716, assigned to Albion International, Inc., issued May 16, 1989. These chelates contain one or more natural amino acids selected from alanine, arginine, asparagine, aspartic acid, cysteine, cystine, glutamine, glutamic acid, glycine, histidine, hydroxyproline, isoleucine, leucine, lysine, methionine, ornithine, phenylalanine, proline, serine, threonine, tryptophan, tyrosine and valine or dipeptides, tripeptides or quadrapeptides formed by any combination of these amino acids.

Typically, wherein magnesium is utilized herein, at least about 1 milligram of magnesium is included per single serving of the composition (typically, about 240 milliliters of total composition). More preferably, when used, at least about 50 milligrams of magnesium is included per single serving of the composition. Most preferably, when used, at least about 100 milligrams of magnesium is included per single serving of the composition. About 400 milligrams of magnesium, per single serving of the composition, is recommended for adult humans. Alternatively, the present compositions comprise from 0% to about 1% magnesium, more preferably from about 0.001% to about 0.8% magnesium, even more preferably from about 0.002% to about 0.6% magnesium, and most preferably from about 0.002% to about 0.5% magnesium, by weight of the composition. As used herein, recitations of mass or weight percent of "magnesium" in any given composition refers to the mass or weight percent of the magnesium-containing component (for example, the amino acid chelated magnesium component), rather than the mass or weight percent of the elemental magnesium which is part of the magnesium-containing component. Of course, wherein elemental magnesium is utilized as the "magnesium", the mass or weight percent of magnesium in any given composition refers to that of the elemental magnesium.

As used herein, "calcium" is inclusive of any compound containing calcium, including a salt, complex, or other form of calcium, including elemental calcium. Acceptable forms of calcium are well-known in the art.

Preferred sources of calcium include, for example, amino acid chelated calcium, calcium carbonate, calcium oxide, calcium hydroxide, calcium sulfate, calcium chloride, calcium phosphate, calcium hydrogen phosphate, calcium dihydrogen phosphate, calcium citrate, calcium malate, calcium titrate, calcium gluconate, calcium realate, calcium tantrate, and calcium lactate, and in particular calcium citrate malate. The form of calcium citrate malate is described in, *e.g.*, Mehansho *et al.*, U.S. Patent No. 5,670,344, issued September 23, 1997; Diehl *et al.*, U.S. Patent

No. 5,612,026, issued March 18, 1997; Andon *et al.*, U.S. Patent No. 5,571,441, issued November 5, 1996; Meyer *et al.*, U.S. Patent No. 5,474,793, issued December 12, 1995; Andon *et al.*, U.S. Patent No. 5,468,506, issued November 21, 1995; Burkes *et al.*, U.S. Patent No. 5,445,837, issued August 29, 1995; Dake *et al.*, U.S. Patent No. 5,424,082, issued June 13, 1995; Burkes *et al.*, U.S. Patent No. 5,422,128, issued June 6, 1995; Burkes *et al.*, U.S. Patent No. 5,401,524, issued March 28, 1995; Zuniga *et al.*, U.S. Patent No. 5,389,387, issued February 14, 1995; Jacobs, U.S. Patent No. 5,314,919, issued May 24, 1994; Saltman *et al.*, U.S. Patent No. 5,232,709, issued August 3, 1993; Camden *et al.*, U.S. Patent No. 5,225,221, issued July 6, 1993; Fox *et al.*, U.S. Patent No. 5,215,769, issued June 1, 1993; Fox *et al.*, U.S. Patent No. 5,186,965, issued February 16, 1993; Saltman *et al.*, U.S. Patent No. 5,151,274, issued September 29, 1992; Kochanowski, U.S. Patent No. 5,128,374, issued July 7, 1992; Mehansho *et al.*, U.S. Patent No. 5,118,513, issued June 2, 1992; Andon *et al.*, U.S. Patent No. 5,108,761, issued April 28, 1992; Mehansho *et al.*, U.S. Patent No. 4,994,283, issued February 19, 1991; Nakel *et al.*, U.S. Patent No. 4,786,510, issued November 22, 1988; and Nakel *et al.*, U.S. Patent No. 4,737,375, issued April 12, 1988.

Typically, wherein calcium is utilized herein, at least about 100 milligrams of calcium is included, per single serving of the composition (typically, about 240 milliliters of total composition). More preferably, when used, at least about 200 milligrams of calcium is included per single serving of the composition. Most preferably, when used, at least about 400 milligrams of calcium is included per single serving of the composition. About 1,000 milligrams of calcium, per single serving of the composition, is recommended for adult humans. Preferred compositions of the present invention will comprise from 0% to about 5% calcium, more preferably from about 0.01% to about 0.5% calcium, still more preferably from about 0.03% to about 0.2% calcium, even more preferably from about 0.05% to about 0.15% calcium, and most preferably from about 0.1% to about 0.15% calcium, by weight of the composition. As used herein, recitations of mass or weight percent of "calcium" in any given composition refers to the mass or weight percent of the calcium-containing component (for example, the amino acid chelated calcium component), rather than the mass or weight percent of the elemental calcium which is part of the calcium-containing component. Of course, wherein elemental calcium is utilized as the "calcium", the mass or weight percent of calcium in any given composition refers to that of the elemental calcium.

As used herein, "selenium" is inclusive of any compound containing selenium, including a salt, complex, or other form of selenium, including elemental selenium. Selenium is useful for immune function. Acceptable forms of selenium are well-known in the art.

Selenomethionine is the principal form of selenium found in foods. Also preferred for inclusion herein are elemental selenium and / or selenium yeast.

Typically, wherein selenium is utilized herein, at least about 10 micrograms of selenium is included, per single serving of the composition (typically, about 240 milliliters of total composition). More preferably, when used, at least about 15 micrograms of selenium is included, per single serving of the composition. Most preferably, when used, at least about 20 micrograms of selenium is included, per single serving of the composition. From about 10 to about 70 micrograms of selenium, per single serving of the composition, is recommended for adult humans. Preferred compositions of the present invention will comprise from 0% to about 0.1% selenium, more preferably from about 0.00001% to about 0.05% selenium, still more preferably from about 0.00001% to about 0.01% selenium, even more preferably 0.00001% to about 0.005% selenium, and most preferably from about 0.00001% to about 0.001% selenium, by weight of the composition. As used herein, recitations of mass or weight percent of "selenium" in any given composition refers to the mass or weight percent of the selenium-containing component (for example, selenomethionine), rather than the mass or weight percent of the elemental selenium which is part of the selenium-containing component. Of course, wherein elemental selenium is utilized as the "selenium", the mass or weight percent of selenium in any given composition refers to that of the elemental selenium.

As used herein, "iodine" is inclusive of any compound containing iodine, including a salt, complex, or other form of iodine, including elemental iodine. Acceptable forms of iodine are well-known in the art. Non-limiting examples of iodine forms include potassium iodide, sodium iodide, potassium iodate, and sodium iodate.

Typically, wherein iodine is utilized herein, at least about 10 micrograms of iodine is included, per single serving of the composition (typically, about 240 milliliters of total composition). More preferably, when used, at least about 15 micrograms of iodine is included, per single serving of the composition. Most preferably, when used, at least about 20 micrograms of iodine is included, per single serving of the composition. From about 10 to about 70 micrograms of iodine, per single serving of the composition, is recommended for adult humans. Preferred compositions of the present invention will comprise from 0% to about 0.1% iodine, more preferably from about 0.00001% to about 0.05% iodine, still more preferably from about 0.00001% to about 0.01% iodine, even more preferably 0.00001% to about 0.005% iodine, and most preferably from about 0.00001% to about 0.001% iodine, by weight of the composition. As used herein, recitations of mass or weight percent of "iodine" in any given composition refers to the mass or weight percent of the iodine-containing component (for example, potassium iodide),

rather than the mass or weight percent of the elemental iodine which is part of the iodine-containing component. Of course, wherein elemental iodine is utilized as the "iodine", the mass or weight percent of iodine in any given composition refers to that of the elemental iodine.

As used herein, "fluorine" is inclusive of any compound containing fluorine, including a salt, complex, or other form of fluorine, including elemental fluorine. Acceptable forms of fluorine are well-known in the art. Non-limiting examples of fluorine forms include sodium fluoride, stannous fluoride, and sodium monofluorophosphate.

Typically, wherein fluorine is utilized herein, at least about 0.001 milligrams of fluorine is included, per single serving of the composition (typically, about 240 milliliters of total composition). More preferably, when used, at least about 0.01 milligrams of fluorine is included, per single serving of the composition. Most preferably, when used, at least about 0.03 milligrams of fluorine is included, per single serving of the composition. Preferred compositions of the present invention will comprise from 0% to about 0.5% fluorine, more preferably from about 0.00001% to about 0.1% fluorine, still more preferably from about 0.0001% to about 0.05% fluorine, even more preferably 0.0001% to about 0.03% fluorine, and most preferably from about 0.0001% to about 0.01% fluorine, by weight of the composition. As used herein, recitations of mass or weight percent of "fluorine" in any given composition refers to the mass or weight percent of the fluorine-containing component (for example, sodium fluoride), rather than the mass or weight percent of the elemental fluorine which is part of the fluorine-containing component. Of course, wherein elemental fluorine is utilized as the "fluorine", the mass or weight percent of fluorine in any given composition refers to that of the elemental fluorine.

#### Emulsions

Dilute juice beverages of the present invention may optionally, but preferably, comprise from about 0.2% to about 5%, preferably from about 0.5% to about 3%, and most preferably from about 0.8% to about 2%, of a beverage emulsion. This beverage emulsion can be either a cloud emulsion or a flavor emulsion.

For cloud emulsions, the clouding agent can comprise one or more fats or oils stabilized as an oil-in-water emulsion using a suitable food grade emulsifier. Any of a variety of fats or oils may be employed as the clouding agent, provided that the fat or oil is suitable for use in foods and / or beverages. Preferred are those fats and oils that have been refined, bleached and deodorized to remove off-flavors. Especially suitable for use as clouding agents are those fats that are organoleptically neutral. These include fats from the following sources: vegetable fats such as soybean, corn, safflower, sunflower, cottonseed, canola, and rapeseed; nut fats such as coconut,



palm, and palm kernel; and synthetic fats. See e.g., Kupper *et al.*, U.S. Patent No. 4,705,691, issued November 10, 1987, for suitable fat or oil clouding agents.

Any suitable food grade emulsifier can be used that can stabilize the fat or oil clouding agent as an oil-in-water emulsion. Suitable emulsifiers include gum acacia, modified food starches (*e.g.*, alkenylsuccinate modified food starches), anionic polymers derived from cellulose (*e.g.*, carboxymethylcellulose), gum ghatti, modified gum ghatti, xanthan gum, tragacanth gum, guar gum, locust bean gum, pectin, and mixtures thereof. See e.g., Kupper *et al.*, U.S. Patent No. 4,705,691, issued November 10, 1987. Modified starches treated to contain hydrophobic as well as hydrophilic groups, such as those described in Caldwell *et al.*, U.S. Patent 2,661,349, are preferred emulsifiers for use as herein. Octenyl succinate (OCS) modified starches such as those described in Marotta *et al.*, U.S. Patent 3,455,838 and Barndt *et al.*, U.S. Patent 4,460,617 are especially preferred emulsifiers.

The clouding agent can be combined with a weighting agent to provide a beverage opacifier that imparts a total or partial opaque effect to the beverage without separating out and rising to the top. The beverage opacifier provides the appearance to the consumer of a juice-containing beverage. Any suitable weighting oil can be employed in the beverage opacifier. Typical weighting oils include brominated vegetable oil, glycerol ester of wood rosin (ester gum), sucrose acetate isobutyrate (SAIB) and other sucrose esters, gum damar, colophony, gum elemi, or others known to those skilled in the art. Other suitable weighting agents include brominated liquid polyol polyesters which are nondigestible. See e.g., Brand *et al.*, U.S. Patent 4,705,690, issued November 10, 1987.

The cloud/opacifier emulsion is prepared by mixing the clouding agent with the weighting agent (for opacifier emulsions), the emulsifier and water. The emulsion typically contains from about 0.1% to about 25% clouding agent, from about 1% to about 20% weighting oil agent (in the case of opacifier emulsions), from about 1% to about 30% emulsifiers, and from about 25% to about 97.9% water (or *quantum satis*).

Flavor emulsions useful in beverage products of the present invention comprise one or more suitable flavor oils, extracts, oleoresins, essential oils and the like, known in the art for use as flavorants in beverages. This component can also comprise flavor concentrates such as those derived from concentration of natural products such as fruits. Terpeneless citrus oils and essences can also be used herein. Examples of suitable flavors include, for example, fruit flavors such as orange, lemon, lime and the like, cola flavors, tea flavors, coffee flavors, chocolate flavors, dairy flavors. These flavors can be derived from natural sources such as essential oils and extracts, or can be synthetically prepared. The flavor emulsion typically comprises a blend of various flavors

and can be employed in the form of an emulsion, alcoholic extract, or spray dried. The flavor emulsion can also include clouding agents, with or without weighting agents, as previously described. See e.g., Kupper *et al.*, U.S. Patent 4,705,691, issued November 10, 1987.

Flavor emulsions are typically prepared in the same manner as cloud/opacifier emulsions by mixing one or more flavoring oils (from about 0.001% to about 20%) with an emulsifying agent (from about 1% to about 30%) and water. (The oil clouding agents can also be present). Emulsions of particles with diameters of from about 0.1 to about 3.0 microns are suitable. Preferably, the particles are about 2.0 microns or less in diameter. Most preferably, the particles are about 1.0 microns or less in diameter. The emulsifying agent coats the particularized flavor oil to aid in preventing coalescence and in maintaining an appropriate dispersion. The viscosity and specific gravity of the flavor emulsion are regulated to be compatible with the finished beverage. See e.g., Kupper *et al.*, U.S. Patent 4,705,691, issued November 10, 1987.

#### Flavoring Agents

One or more flavoring agents are recommended for the embodiments of the present invention in order to enhance their palatability. Any natural or synthetic flavor agent can be used in the present invention. For example, one or more botanical and / or fruit flavors may be utilized herein. As used herein, such flavors may be synthetic or natural flavors.

Particularly preferred fruit flavors are exotic and lactonic flavors such as, for example, passion fruit flavors, mango flavors, pineapple flavors, cupuacu flavors, guava flavors, cocoa flavors, papaya flavors, peach flavors, and apricot flavors. Besides these flavors, a variety of other fruit flavors can be utilized such as, for example, apple flavors, citrus flavors, grape flavors, raspberry flavors, cranberry flavors, cherry flavors, grapefruit flavors, and the like. These fruit flavors can be derived from natural sources such as fruit juices and flavor oils, or may alternatively be synthetically prepared.

Preferred botanical flavors include, for example, tea (preferably black and green tea, most preferably green tea), aloe vera, guarana, ginseng, ginkgo, hawthorn, hibiscus, rose hips, chamomile, peppermint, fennel, ginger, licorice, lotus seed, schizandra, saw palmetto, sarsaparilla, safflower, St. John's Wort, curcuma, cardimom, nutmeg, cassia bark, buchu, cinnamon, jasmine, haw, chrysanthemum, water chestnut, sugar cane, lychee, bamboo shoots, vanilla, coffee, and the like. Preferred among these is tea, guarana, ginseng, ginko, and coffee. In particular, the combination of tea flavors, preferably green tea or black tea flavors (preferably green tea), optionally together with fruit flavors has an appealing taste. In another preferred embodiment, coffee is included within the present compositions. A combination of green tea and coffee in the present compositions is often preferred.

The flavor agent can also comprise a blend of various flavors. If desired, the flavor in the flavoring agent may be formed into emulsion droplets which are then dispersed in the beverage composition or concentrate. Because these droplets usually have a specific gravity less than that of water and would therefore form a separate phase, weighting agents (which can also act as clouding agents) can be used to keep the emulsion droplets dispersed in the beverage composition or concentrate. Examples of such weighting agents are brominated vegetable oils (BVO) and resin esters, in particular the ester gums. See L.F. Green, Developments in Soft Drinks Technology, Vol. 1, Applied Science Publishers Ltd., pp. 87-93 (1978) for a further description of the use of weighting and clouding agents in liquid beverages. Typically the flavoring agents are conventionally available as concentrates or extracts or in the form of synthetically produced flavoring esters, alcohols, aldehydes, terpenes, sesquiterpenes, and the like.

#### Coloring Agent

Small amounts of one or more coloring agents may be utilized in the compositions of the present invention. FD&C dyes (*e.g.*, yellow #5, blue #2, red # 40) and / or FD&C lakes are preferably used. By adding the lakes to the other powdered ingredients, all the particles, in particular the colored iron compound, are completely and uniformly colored and a uniformly colored beverage mix is attained. Preferred lake dyes which may be used in the present invention are the FDA-approved Lake, such as Lake red #40, yellow #6, blue #1, and the like. Additionally, a mixture of FD&C dyes or a FD&C lake dye in combination with other conventional food and food colorants may be used. Riboflavin and b-carotene may also be used. Additionally, other natural coloring agents may be utilized including, for example, fruit, vegetable, and / or plant extracts such as grape, black currant, aronia, carrot, beetroot, red cabbage, and hibiscus.

The amount of coloring agent used will vary, depending on the agents used and the intensity desired in the finished product. Generally, if utilized, the coloring agent should be present at a level of from about 0.0001% to about 0.5%, preferably from about 0.001% to about 0.1%, and most preferably from about 0.004% to about 0.1%, by weight of the composition.

#### Preservatives

Preservatives may or may not be needed for use in the present compositions. Techniques such as aseptic and / or clean-fill processing may be utilized to avoid preservatives.

One or more preservatives may, however, optionally be added to the present compositions. Preferred preservatives include, for example, sorbate, benzoate, and polyphosphate preservatives (for example, sodium hexametaphosphate).

Preferably, wherein a preservative is utilized herein, one or more sorbate or benzoate preservatives (or mixtures thereof) are utilized. Sorbate and benzoate preservatives suitable for

use in the present invention include sorbic acid, benzoic acid, and salts thereof, including (but not limited to) calcium sorbate, sodium sorbate, potassium sorbate, calcium benzoate, sodium benzoate, potassium benzoate, and mixtures thereof. Sorbate preservatives are particularly preferred. Potassium sorbate is particularly preferred for use in the present invention.

Wherein a composition comprises a preservative, the preservative is preferably included at levels from about 0.0005% to about 0.5%, more preferably from about 0.001% to about 0.4% of the preservative, still more preferably from about 0.001% to about 0.1%, even more preferably from about 0.001% to about 0.05%, and most preferably from about 0.003% to about 0.03% of the preservative, by weight of the composition. Wherein the composition comprises a mixture of one or more preservatives, the total concentration of such preservatives is preferably maintained within these ranges.

#### Water

Water is not necessary for dry beverage compositions (as used herein, "dry beverage compositions" are substantially dry (meaning, comprising from 0% to about 4%, preferably from 0% to about 3% water) compositions which are suitable for dilution with water or other liquids to form a concentrated or ready-to-drink beverage composition. Since dry beverage compositions will be diluted with water or another liquid prior to consumption, the benefits of the present invention, for example, stability of a combination containing both fiber and protein, are still realized.

Therefore, the compositions may comprise from 0% to about 99.999% water, by weight of the composition. Beverage compositions which are not "dry beverage compositions" typically comprise at least about 4% water, preferably at least about 20% water, more preferably at least about 40% water, still more preferably at least about 50% water, even more preferably at least about 75% water, and most preferably at least about 80% water. Still further, ready-to-drink beverage compositions will typically comprise at least about 50% water. The water included at these levels includes all added water and any water present in combination components, for example, fruit juice.

#### Carbonation Component

Carbon dioxide can be introduced into the water which is mixed with a beverage concentrate or into a beverage composition after dilution to achieve carbonation. The carbonated beverage can be placed into a container, such as a bottle or can, and then sealed. Any conventional carbonation methodology may be utilized to make carbonated beverage compositions of this invention. The amount of carbon dioxide introduced into the beverage will depend upon the particular flavor system utilized and the amount of carbonation desired.

### Methods of Making the Present Compositions

The present compositions can be made according to various methods. In a preferred method of making, it has been discovered that the present compositions may be made in accordance with the processes described in U.S. Patent no. 5,648,112, Yang *et al.*, issued July 15, 1997, except with a substitution of the arabinogalactan for the food stabilizer described therein. Alternatively or additionally, it has been presently discovered that preferred protein stabilization is achieved wherein the high shear mixing as mentioned in Yang *et al.* is performed at a mixing energy of at least about 15 Watts / kilogram of the composition, more particularly at least about 25 Watts / kilogram of the composition. Various other modifications of such process could also be made.

Other methods useful herein will be well-known to the ordinarily skilled artisan. To illustrate, the compositions of the present invention may be prepared by dissolving, dispersing, or otherwise mixing all components singularly or in suitable combinations together and in water where appropriate, agitating with a mechanical stirrer until all of the ingredients have been solubilized or adequately dispersed. Where appropriate, all separate solutions and dispersed may then be combined. Wherein a shelf stable composition is desired, the final mixture can optionally, but preferably, be pasteurized or filled aseptically at appropriate process conditions.

In making a beverage composition, a beverage concentrate may optionally be formed first. One method to prepare the concentrate form of the beverage composition would be to start with less than the required volume of water that is used in the preparation of the beverage composition. Another method would be to partially dehydrate the finally prepared beverage compositions to remove only a portion of the water and any other volatile liquids present. Dehydration may be accomplished in accordance with well-known procedures, such as evaporation under vacuum. The concentrate can be in the form of a relatively thick liquid. A syrup is typically formed by adding suitable ingredients such as electrolytes or emulsions to the beverage concentrate. The syrup is then mixed with water to form a finished beverage or finished beverage concentrate. The weight ratio of water to syrup is typically from about 1:1 to about 5:1.

Carbon dioxide can be introduced either into the water to be mixed with the beverage concentrate, or into the drinkable beverage composition, to achieve carbonation. The carbonated beverage composition can then be stored in a suitable container and then sealed. Techniques for making and carbonating beverage embodiments of the present invention are described in the following references: L.F. Green (ed.), *Developments in Soft Drinks Technology*, Vol. 1 (Elsevier, 1978); G.S. Cattell and P.M. Davies, "Preparation and Processing of Fruit Juices, Cordials and

Drinks", *Journal of the Society of Dairy Technology*, Vol. 38 (1), pp. 21-27, A.H. Varnam and J.P. Sutherland, *Beverages - Technology, Chemistry and Microbiology*, Chapman Hall, 1994; and A.J. Mitchell (ed.), *Formulation and Production of Carbonated Soft Drinks*, Blackie and Sons Ltd., 1990.

Dry beverage compositions of the present invention can of course be made herein. As used herein, dry beverage compositions (as used herein, "dry beverage compositions" are substantially dry (meaning, comprising from 0% to about 4%, preferably from 0% to about 3% water) compositions which are suitable for dilution with water or other liquids to form a concentrated or ready-to-drink beverage composition. Dry beverage compositions may be prepared by blending the proper amounts and ratios of all the required dry ingredients together. Alternatively, the finally prepared beverage compositions can be dehydrated to give a dry beverage composition of the present invention. The dry beverage composition, either as, for example, a powder, granules or tablets, can later be dissolved in a proper amount of water or other liquid, carbonated or non-carbonated, to make the beverage concentrate or ready-to-drink beverage composition. Alternatively, dry forms of the present invention may be incorporated in other compositions, including but not limited to cereal bars, breakfast bars, energy bars, and nutritional bars.

Other essentially dry compositions include, for example, tablets, capsules, granules, and dry powders. Tablets may contain suitable binders, lubricants, diluents, disintegrating agents, coloring agents, flavoring agents, flow-inducing agents, and melting agents. Suitable carriers and excipients that may be used to formulate dry forms of the present invention are described in, for example, Robber, U.S. Patent No. 3,903,297, issued September 2, 1975. Techniques and compositions for making dry forms useful in the methods of this invention are described in the following references: H.W. Houghton (ed.), *Developments in Soft Drinks Technology*, Vol. 3, Chapter 6, (Elsevier, 1984); *Modern Pharmaceutics*, Chapters 9 and 10 (Banker & Rodas (ed.), 1979); Liberman et al., *Pharmaceutical Dosage Forms: Tablets* (1981); and Ansel, *Introduction to Pharmaceutical Dosage Forms*, 2nd Ed., (1976).

EXAMPLES

The following are non-limiting examples of compositions used in accordance with the present invention. The compositions are prepared utilizing conventional methods. The following examples are provided to illustrate the invention and are not intended to limit the scope thereof in any manner.

Example 1

A composition is prepared having the following ingredients in the indicated amounts:

<b>Ingredient</b>	<b>Weight Percent</b>
Milk (2% fat)	98%
Arabinogalactan	2%

Upon preparing the composition, it is observed that inclusion of the fiber does not cause gelling, grit, or precipitation. In comparison, a similar composition containing psyllium gels and is not suitable for use.

Example 2

A milk powder composition is prepared having the following ingredients in the indicated amounts:

<b>Ingredient</b>	<b>Weight Percent</b>
Granular sucrose	62
Cocoa	4.9
Non-dairy Creamer	19.5
Vitamins	0.4
Ferrous fumarate	0.05
Arabinogalactan	13.15

The milk powder is added to 240 milliliters of water at about 100 °C to make a finally consumed beverage. No significant off-color development is observed after a twenty-four hour period as measured by a standard Hunter Color Difference Meter.

Example 3

A powdered chocolate milk beverage is prepared having the following ingredients in the indicated amounts:

<b>Ingredient</b>	<b>Weight Percent</b>
Granular Sucrose	62
Cocoa	4.8
Non-dairy Creamer	20

SUNACTIVE Iron	0.2
Arabinogalactan	13

A ready-to-drink beverage composition is further prepared by adding 240 milliliters of hot water to the powdered chocolate milk. A Hunter Color Difference Meter shows that the arabinogalactan prevents any off-color development, particularly as compared against compositions which are similar in all respects but for the absence of the arabinogalactan.

#### Example 4

A snack beverage is prepared having the following ingredients in the indicated amounts:

Ingredient	Weight Percent
Soy Protein	0.88
FIBER AID Arabinogalactan (Larex, Inc., White Bear Lake, MN, USA)	0.7
Glucono Delta Lactone (acidifier)	0.9
Flavor Oil	0.01
Ethyl Oleate	1.13
Calcium-L-acetate	0.4
Suspension Agent	0.4
Artificial Flavors	0.29
Acesulfame K	0.025
Sucralose	0.012
Colors	0.004
Water	<i>Quantum satis</i>

The composition is prepared by first mixing the soy protein and the arabinogalactan in about one-half of the total water. The glucono delta lactone in about one-fifth of the total water is then added followed by the ethyl oleate and flavor oil, finally followed by the remaining ingredients. Mixing is utilized throughout all addition steps. A 355 gram serving of the snack composition is ingested once daily to deliver various benefits, including a fiber benefit and satiety induction.

#### Example 5

An acidified milk beverage is prepared having the following ingredients in the indicated amounts:

Ingredient	Weight Percent
Milk Powder	0.5
Arabinogalactan AG99 (Larex, Inc., White Bear Lake, MN, USA)	1.75
Citric Acid	0.45
Sodium Citrate	0.1
Dow Corning ANTIFOAM 1520US	<i>As needed</i>



Water	<i>Quantum satis</i>
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The beverage is prepared by the direct acidification of the composition in a 4 Liter Waring Blender with net-power-per-unit mass of about 67 Watt/Kg of the composition, which is greater than the blender's minimum required 25 Watt/Kg of the composition. The blending process is conducted using the following steps: a) add water, b) add the arabinogalactan, c) mix for 3 minutes, d) add the milk powder, e) mix for 3 minutes, f) add the sodium citrate, g) slowly add the citric acid, h) add the ANTIFOAM and i) mix for 3 minutes. The finished beverage is stable for more than two months with minimal, if any, sedimentation and coagulation.

#### Example 6

An orange juice beverage of the present invention is prepared using a method similar to that set forth in Example 5, having the following ingredients in the indicated amounts:

Ingredient	Weight Percent
Skim milk (non-fat)	5
Sweetener	12
Orange Juice	5
Arabinogalactan AG99 (Larex, Inc., White Bear Lake, MN, USA)	1.75
Citric Acid	0.45
Sodium Citrate	0.1
Orange Flavors	0.17
Dow Corning ANTIFOAM 1520US	<i>As needed</i>
Water	<i>Quantum satis</i>

## WHAT IS CLAIMED IS:

1. A composition characterized by:
  - a) a first component which is arabinogalactan; and
  - b) a second component which is selected from the group consisting of dairy protein, soy protein, and mixtures thereof;

wherein when the second component comprises dairy protein, the composition is substantially free of yogurt.

2. A composition according to Claim 1 which is a beverage composition having a pH from about 2 to about 5.
3. A composition according to Claim 1 which is a beverage composition having a pH from about 5 to about 8.
4. A composition according to any of the preceding claims characterized by from about 0.1% to about 4% of the arabinogalactan, by weight of the composition.
5. A composition according to any of the preceding claims wherein the second component comprises dairy protein.
6. A composition according to any of the preceding claims wherein the second component comprises soy protein.
7. A composition according to any of the preceding claims comprising a juice selected from the group consisting of fruit juice, vegetable juice, and mixtures thereof.
8. A composition according to any of the preceding claims further characterized by a nutrient selected from the group consisting of vitamins, minerals, and mixtures thereof.
9. A composition according to any of the preceding claims wherein when the composition is characterized by soy protein, the composition is substantially free of yogurt.

10. A composition according to any of the preceding claims which is further characterized by an oil.